REMARKS

I. Status of the Claims

Claims 1-91 are pending, with claims 48-91 being added herein.

II. The Amendments Herein

No new matter has been added by the present amendments.

The amendments to claim 1 correct the punctuation and improve the antecedence of the claim language by changing the phrase "a first reagent solution" to "the first reagent solution." Since the term "first reagent solution" was introduced in line 3 of the claim, changing the "a" to "the" more correctly identifies the solution referred to.

The amendment to claim 2 corrects a problem in terminology so that claim 3 is properly dependent.

New claims 48, 49, and 91 refer to a method of claim 1, a method of claim 15, and an apparatus of claim 41 in which the non-stick material is selected from a silane and a siloxane. The use of silanes and siloxanes as non-stick materials is supported throughout the specification. For example, at page 8, lines 3-7, the specification notes that among the non-stick coatings known to those of skill in the art are silanes. The use of siloxanes is likewise supported throughout the specification. The specification contains a number of working examples demonstrating the use of an exemplar siloxane (referred to in the specification by its trade name, Gel Slick™). *See, e.g.*, Example 2, page 18, lines 6-8. In the Amendment, Applicants pointed out that Gel Slick™ is a solution of dimethyl siloxane.

New claims 50-90 are identical to original claims 1-40 (as amended in the previous amendment and herein), but specify that the solid support is contacted with the non-stick material after contacting the solid support with the first reagent solution. Support for contacting the solid support with the non-stick material after contacting with the first reagent solution is supported throughout the specification, including Example 3, page 19, line 8 through page 21, Table 4.

Applicants note for the record that none of the amendments are made for reasons related to patentability.

III. Withdrawal of Rejections

Applicants note with appreciation the withdrawal of all rejections set forth in the previous office action, as well as the indication that the claims will be allowed following addressing of the Action's concerns under 35 U.S.C. § 112, second paragraph. The concerns regarding §112, and Applicants' response thereto, are discussed below.

IV. The Rejection

The Action rejects claims 1-47 under 35 U.S.C. §112, second paragraph, as allegedly indefinite. According to the Action,

> Claims 1-47 are indefinite at [reciting] "a non-stick material" because the examples at page 8 of the specification are ambiguous and it cannot be determined what is encompassed by the "non-stick material" or the specificity of the non-stick material to a target sample. For example, it cannot be clearly determined whether any "non-stick material" such as a cooking spray is capable of functioning in the claimed invention. It is suggested amending the claims 1, 15, and 41 to recite the non-stick materials recited in claims 13, 17, and 43 for clarity.

Action, at page 3. Applicants traverse.

Applicants respectfully call the Examiner's attention to MPEP § 2173.02 (8th Ed., Feb. 2003 revision) (all citations herein are to this revision of the MPEP). Section 2173.02 instructs the Examining Corps that claims should be allowed which

> define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even if the claim language is not as precise as the Examiner might wish.

MPEP at page 2100-198-199, bridging paragraph (emphasis in original). Section 2173.02 gives the Examining Corps the following instructions:

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum but in light of:
>
> (A) The content of the particular application disclosure;
>
> (B) The teachings of the prior art; and
>
> (C) The claim interpretation that would be given by one possessing the ordinary level skill in the pertinent art at the time the invention was made.
>
> In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art as of its scope and, therefore, serves the notice function required by 35 U.S.C. 112 second paragraph by providing clear warning to others as to what constitutes infringement of the patent.

MPEP §2173.02, at page 2100-199 (emphasis added).

Applicants respectfully maintain that the present rejection does not follow the analysis required by the MPEP. For example, the Action provides no analysis or reasoning why a person of ordinary skill in the art, typically in this art at least a Bachelor's level scientist or technician proficient in PCR or other amplification technologies, would be unable to determine what constitutes a "non-stick material." Certainly, the Action does not indicate the interpretation that would be given to the term by a person of ordinary skill or why that interpretation would be deficient in giving notice as to what would constitute infringement of the patent.

Applicants further note that the rejection ignores:

(1) a functional recitation in the claims: "wherein cross-contamination of the second reagent solution by the first reagent solution is reduced by coating the solid support with a non-stick material," and

(2) the fact that the Examples set forth detailed assays by which the practitioner can determine whether any particular proposed non-stick material succeeds in reducing cross-contamination.

Applicants submit that the existence of the recitation, coupled with the assays set forth in the Examples, permit the practitioner to readily determine whether any particular material falls within the scope of the claims. And, as quoted above, the MPEP states that "[s]ome latitude in the manner of expression and the aptness of terms should be permitted even if the claim language is not as precise as the Examiner might wish."

The Action does assert that the specification's teachings regarding non-stick materials at page 8 is ambiguous. But, the Action simply presents a conclusion, not the analysis required by the MPEP. Applicants respectfully note that this conclusion does not take into account the functional recitation in the claims, the assays taught in the specification, or the interpretation that would be given by the person of ordinary skill. As quoted above, MPEP s2173.02 requires only a reasonable degree of clarity and particularity. The Action fails to show that the clarity of the term "non-stick material" lacks either a reasonable degree of clarity or a reasonable degree of particularity.

The Action does offer one concrete example that it believes exemplifies the indefiniteness it finds in the claims: the Action states that "it cannot be clearly determined whether any 'non-stick material' such as a cooking spray is capable of functioning in the claimed invention." Action, at page 3. This statement is incorrect for three different reasons.

First, as already noted, the Examples in the specification (such as Examples 2 and 3) set forth assays by which the practitioner can readily determine whether any particular non-stick material is satisfactory for satisfying the functional recitation that the material reduce cross-contamination. For example, any particular non-stick material to be tested for its ability to reduce cross-contamination by substituting it in the assays taught in Example 4 for the silane or GelSlick™ used in those assays and measuring the number of drop-outs and degree of substrate precipitation. Thus, contrary to the Action's assertion, it is actually quite easy for the practitioner

to determine whether any particular putative non-stick material is capable of functioning in the claimed invention.

Second, the "cooking spray" hypothetical posed by the Action, presumably to show the alleged indefiniteness of the claims, does nothing of the kind. Applicants respectfully note that the film of oil left by a cooking spray might very well reduce cross-contamination when used as a non-stick coating material in PCR and other nucleic acid amplification processes. The reason commercial cooking sprays are not likely to be used for this purpose is unrelated to whether or not they are non-stick materials: since cooking oils are not prepared with laboratory use in mind, they are likely to contain materials (such as stray skin cells from the workers) which could create artifacts or otherwise interfere with the accuracy of results in PCR and other assays, which are very sensitive. Cooking sprays made to laboratory reagent standards, however, would likely be usable in the claimed methods. Any particular cooking spray can, as noted above, readily be tested in the assays set forth in the Examples to determine if it satisfies the functional recitation in the claims.

Third, the "cooking spray" hypothetical posed by the Action itself shows the infirmity of the rejection. In citing "cooking spray" as a non-stick material, the Action itself shows that there is no ambiguity or uncertainty as to the meaning of the term "non-stick material"; the rejection is really that the Action does not believe a cooking spray would work in the claimed methods. As set forth above, however, the Action ignores both a functional recitation in the claims and assays by which any particular putative non-stick material, such as a cooking spray, can be tested for its suitability.

Finally, Applicants note that the Action is internally inconsistent. As set forth in the rejection, the Action contends that claims 1, 15, and 41 should be amended to recite the specific non-stick materials recited in claims 13, 17 and 43. Yet, claims 13, 17, and 43 are themselves rejected as indefinite. Thus, the rejection is overbroad even on its own terms.

In short, the Action presents no evidence that there would be any confusion or lack of notice that would, in the words of the MPEP, fail to provide "clear warning to others as to what constitutes infringement of the patent." To the contrary, the term "non-stick material" is well understood, both by the artisan and by the layperson. Persons of skill are therefore given "clear warning to others as to what constitutes infringement of the patent," and the purposes of

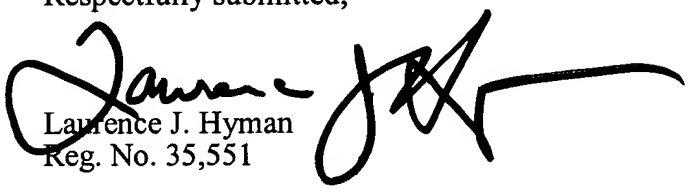
the requirements of §112, second paragraph have been met. As noted at the beginning of this section, MPEP 2173.02 instructs that claims should be allowed that "define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even if the claim language is not as precise as the Examiner might wish." The rejection should be reconsidered using this the MPEP's standard and, upon reconsideration, should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, she is invited to telephone the undersigned at 415-576-0200.

Respectfully submitted,



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MARKED UP VERSION SHOWING CORRECTIONS

1. (Amended) A method of reducing cross-contamination of an assay reagent solution, the method comprising:

contacting a solid support with a first reagent solution;

removing the solid support from contact with the first reagent solution; and

contacting the solid support with a second reagent solution;

wherein cross-contamination of the second reagent solution by the first reagent solution is reduced by coating the solid support with a non-stick material prior to contacting the solid support with ~~a~~ the first reagent solution.

2. (Amended) The method of claim 1, wherein the solid support is contacted with one or more intermediate ~~reagent~~ solutions prior to contacting the solid support with the second reagent solution.